08-24-04 AF/1625 IFW

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF APPEALS & PATENT INTERFERENCES

Applicants:	R.K. Bakshi, et al.	Art Unit: 1625
Serial No.:	09/990,499 (Case No. 20385YDA)	
Filed:	November 21, 2001	Examiner: D. M. Seaman
For:	SUBSTITUTED PIPERIDINES AS MELANOCORTIN-4 RECEPTOR AGONISTS	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 CFR 1.193(b)

Sir:

Appellants wish to address the following new points of argument raised by the Examiner in the Examiner's Answer marked June 22, 2004, having an unextended 2-month reply date of Monday, August 23, 2004; August 22, 2004 being a Sunday.

EXPRESS MAIL CERTIFICATE
DATE OF DEPOSIT August 23, 2004
EXPRESS MAIL NO. EV321982112US
I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS EXPRESS MAIL "POST OFFICE TO ADDRESSEE" ON THE ABOVE DATE IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450.
MAILED BY Lori Scheller
DATE August 23, 2004

In disagreeing with Appellants' grouping of Claims on Appeal, the Examiner stated that Claims 39-73 encompass oral treatment as well as other treatment options, and that oral treatment is the most widely used for treatment of similar dysfunctions.

Appellants respectfully submit that the Claims of Groups I and II are considered to be separately patentable and do not stand or fall together. Claims 74-75 are a narrower subset of Claims 39-73, and as such would not necessarily be infringed if Claims 39-73 are infringed. Thus, the use of a selective melanocortin-4 receptor agonist to treat male erectile dysfunction (MED) administered by a non-oral (parenteral) route would fall within the scope of Claims 39-73, but outside the scope of claims 74-75.

Appellants respectfully request that the Group I Claims 39-73 and the Group II Claims 74-75 be treated separately for this appeal.

§121 Double Patenting Rejection

The Examiner upheld the rejection of Claims 39-75 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-25 of US Patent No. 6,350,760, and in particular noted that the compound of line 40, column 82 of the patent is the cis/trans stereoisomer of the elected species.

Appellants respectfully request that the obviousness-type double patenting rejection be withdrawn. The present application is a divisional application of US Patent No. 09/585,111 (USSN 09/585,111). In the prosecution of USSN 09/585,111, the Examiner allowed Claims 1-18, 20-25 and 64, and indicated in the Examiner's Amendment of September 19, 2001 that the allowance of these Claims was contingent on restriction of the application to one of the following inventions under 35 USC § 121:

Group I: Claims 1-18, 20-25 and 64 drawn to compounds and methods of using compounds of formula (I), classified in Class 546, subclass 146.

Group II: Claims 26-63, drawn to methods of treating sexual dysfunction by using a melanocortin 4 receptor agonist not encompassed by Claim 1, classified in class 514, subclass various.

The Examiner indicated that these inventions were distinct and acquired a separate status in the art as shown by their different classification, and that restriction for examination purposes as indicated was proper.

In the prosecution of the parent USSN 09/585,111, a provisional election to prosecute Group I (Claims 1-18, 20-25 and 64) was made, and these Claims were subsequently allowed in US Patent No. 6,350,760. Claims 39-75 of the present application correspond to Claims 26-63 of USSN 09/585,111. The instant application is a divisional application of USSN 09/585,111, filed prior to the grant of US Patent No. 6,350,760.

Because the divisional application was filed in compliance with the restriction requirement above, the double patenting rejection is improper under 35 USC 121 (MPEP 804.01). Appellants submit that in USSN 09/585,111 the Restriction Requirement was based on the Examiner's assessment that Group I (Claims 1-18, 20-25 and 64) and Group II (Claims 26-63) corresponded to distinct inventions. Appellants elected Group I and prosecuted the Group I Claims first in reliance on the Examiner's Restriction Requirement. The present application is a divisional of application USSN 09/585,111, and the present Claims 39-75 correspond to the Group II Claims of USSN 09/585,111. Therefore, the double patenting rejection of Claims 39-75 over Claims 1-25 of US Patent No. 6,350,760 is improper.

Based on the foregoing argument, the Appellants respectfully request that the obviousness-type double patenting rejection be withdrawn.

§112, First Paragraph, Rejection for Written Description

In reference to the rejection under 35 U.S.C. §112, first paragraph, the Examiner stated that Claims 39-73 and 74-75 contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner has applied the incorrect standard. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention [Vas Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116]. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention [Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406]. A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the Claims and determined that the invention would work for its intended purpose [Cooper v. Goldfarb, 154, F.3d 1321, 1327; 47 USPQ2d 1896, 1901 (Fed. Cir. 1998)]. Appellants were in possession of the present invention at the time of filing, and that possession is shown based on actual reduction to practice. The Appellants disclose compounds of structural formula I that are selective melanocortin-4 receptor agonists with binding profiles that meet the Claim limitations. Claims 39-75 are directed to the use of selective melanocortin 4 receptor agonists with specific binding affinities and functional activities for the melanocortin 4 receptor relative to the melanocortin 1, 2, 3, and 5 receptors. Claims 39-73 and 74-75 do not encompass "any compound that is a melanocortin 4 receptor agonist" as the Examiner has stated. Furthermore, the compound disclosed in Example 84 is a working example which clearly illustrates the operability of the present invention and the utility of the compound to induce penile erections.

Appellants submit that the specification of the present application describes distinguishing and identifying characteristics sufficient to show that the Appellants were in possession of the claimed invention. Based on Enzo Biochem, an applicant may show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when

coupled with known or disclosed correlation between function and structure, or some combination of such characteristics [Enzo Biochem, 323 F.3d at 964; 63 USPQ2d at 1613]. The following identifying characteristics, which provide evidence that the Appellants were in possession of the invention, were disclosed in the specification: 1) structures of compounds that can be used in the methods of the present invention, including compounds of formula I and the compound of Example 84; 2) the chemical properties of the types of compounds useful in the methods of the present invention, such as their ability to bind to and activate the melanocortin 4 receptor in preference to the other melanocortin receptors; 3) the functional characteristics of the types of compounds useful in the methods of the present invention, such as their ability to activate the melanocortin 4 receptor. In addition to the compounds of formula I being useful as melanocortin 4 receptor agonists, privileged structures and their affinity for G-protein coupled receptors were appreciated in the medicinal chemical arts at the time of filing of Appellants' patent application. Hence, in the art there were and continue to be definite structural characteristics for recognizing candidate compounds with the potential to function as selective melanocortin-4 receptor agonists.

For the above reasons and the reasons put forward in the Appeal Brief, the Appellants submit that their specification contains an adequate written description of their invention to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and therefore, the rejection under §112, first paragraph, for lack of written description should be withdrawn.

§112, First Paragraph, Rejection for Lack of Enablement

In reference to the rejection under 35 U.S.C. §112, first paragraph, the Examiner further stated that Claims 39-73 and 74-75 contain subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains to make and/or use the invention. The Examiner's position is that the specification does not enable the ordinary practitioner of the pertinent art to choose a compound other than one specifically

disclosed in the subject application, namely a substituted isoquinoline of structural formula I in the specification.

The Examiner has improperly applied the test for enablement. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent, coupled with information known in the art, without undue experimentation [In re Buchner, 929 F.2d 660 (C.A. Fed., 1991)]. Appellants submit that one of ordinary skill in the art would have understood that the term "melanocortin 4 receptor agonist" is not limited to the specific agonists disclosed in the specification, and that other selective melanocortin 4 receptor agonists could be used. Appellants have provided guidance and direction in the specification as to which types of compounds would be useful to treat MED, namely, selective melanocortin 4 receptor agonists. Utility of the compounds to treat MED is not based on their particular structure; rather it is based on their chemical properties, i.e., their ability to selectively bind to and activate the melanocortin 4 receptor.

One reasonably skilled in the art could make or use the invention from the disclosures in the specification coupled with information known in the art without undue experimentation. As previously discussed, privileged structures and their affinity for G-protein coupled receptors were appreciated in the medicinal chemical arts at the time of filing of Appellants' patent application. Substituted piperidines of formula (I) were merely one class of such privileged structure scaffolds known in the G-protein-linked receptor art at that time. Other structurally diverse variants outside the scope of formula (I) make up a rich pool of compounds from the G-protein-linked receptor art for evaluation according to the methods described in the instant application. They include *inter alia* compounds having a 1,1-diphenylmethyl, benzodiazepine, biphenyl, tricyclic aromatic, 4-arylpiperidine and spiro versions thereof (such as spiroindanylpiperidine), 4-arylpiperazine, peptidyl, and peptidomimetic structural motifs. Thus, guidance for the selection of compounds beyond those of formula (I) that would fulfill the requirements of Claims 39-75 was and continues to be provided by the art. There exist definite structural characteristics for recognizing candidate compounds with the potential to function as

selective melanocortin-4 receptor agonists in the art, thereby providing clear guidance with respect to how to choose a compound outside the scope of formula (I).

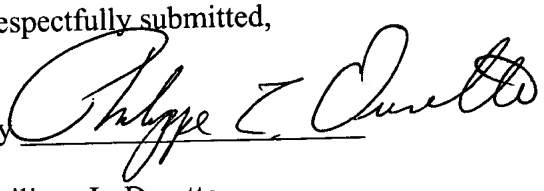
In contrast to the patentee in Univ. of Rochester v. G.D. Searle, Appellants have provided specific compounds useful to practice the claimed method, and, at the time of filing, the art provided additional guidance about the compounds useful to practice the methods of the invention. The Rochester Court held that written description of a claimed method of treatment is not adequate where a compound that is necessary to practice the method is described only in terms of its function, and where the only means provided for finding such a compound is essentially a trial and error process [See Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004)]. The Rochester Court stated that the Rochester patent did not provide guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods and did not provide evidence that any such compounds were within the knowledge of a person of ordinary skill in the art at the relevant time. In the instant application, specific compounds useful to practice the method are disclosed and that guidance as to other compounds, such as compounds with 1,1-diphenylmethyl, benzodiazepine, biphenyl, tricyclic aromatic, 4-arylpiperidine and spiro versions thereof (such as spiroindanylpiperidine), 4-arylpiperazine, peptidyl, and peptidomimetic structural motifs, that could be used in the methods of the present invention was provided in the art at the time of filing.

Since the Appellants' specification does indeed teach one of ordinary skill how to identify selective melanocortin-4 agonists and how to use them to treat MED, the Appellants submit that the enablement contained therein is fully commensurate in scope with Claims 39-73 and 74-75.

For the foregoing reasons, Appellants maintain that their application contains a written description of the invention in sufficient terms to allow one skilled in the art to know what was invented and thus were in possession of the claimed invention at the time the application was filed and, moreover, that their specification fully enables one skilled in the art to make and use the claimed invention without undue experimentation. It is therefore respectfully requested that

the Board of Appeals reverse the Examiner's rejection of Claims 39-73 and 74-75 under 35 U.S.C. §112, first paragraph and under 35 U.S.C. §121.

Respectfully submitted,

By 

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Date: August 23, 2004